

(s)(1) *Nursing home* means an independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature, or location of the medical service provided by the nursing home.

(t)(1) *Outpatient diagnostic facility* means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients;

(ii) Does not assume ongoing responsibility for patient care; and

(iii) Provides its services for use by other medical personnel. (Examples include diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography and in-vitro testing).

(2) An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

(u)(1) *Outpatient treatment facility* means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse.

(2) An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(v) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. For the purposes of this part, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(w) *Physician's office* means a facility that operates as the office of a physician or other health care professional (e.g., dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(x) [Reserved]